

PATENT

ATTORNEY DOCKET NO. DASL002.03US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **Scherrmann et al.**

Serial No.: **Not Yet Assigned**

Filed: **January 9, 2002**

For: **Cocaethylene Immunogens and Antibodies**

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Examiner: Not Yet Assigned

Art Unit: Not Yet Assigned

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION

Assistant Commissioner of Patents

PO Box 2327

Arlington, VA 22202

Sir:

Prior to examination of the above-referenced patent application, the Examiner is respectfully requested to make the amendments shown on the attached "Version with Markings to Show Changes Made".

AMENDMENTS

In the Specification

On page 1, line 1 insert the following section titled "CROSS-REFERENCE TO RELATED APPLICATIONS"

--This application is a continuation of USSN 09/477,269, filed January 4, 2000, which is a

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Robert Pattison

(Signature)

Robert Pattison

(Printed Name)

Jean-Michael Scherrmann *et al.*
Serial No. Not Yet Assigned

continuation of USSN 09/139,536, filed August 25, 1998, which issued September 5, 2000, as USPN 6,114,508, which is a continuation of USSN 08/821,895, filed March 21, 1997, which issued November 6, 1998, as USPN 5,817,770, which disclosures are incorporated herein by reference.--

In the Claims

Pursuant to 37 CFR §1.121, amendments made to the claim 6 and 7 and new claims 13-25 are shown on separately attached "Clean Copy of the Pending Claims". Also attached is a "Version with Markings to Show Changes Made to the Claims".

REMARKS

In the Claims:

New claims 13-26 were added. Claims 1-12 were cancelled.

Claims 13-25 were added. Support for new claim 13 is found on p. 6 lines 28-31 and p. 7 lines 1-4. Support for new claim 14 is found on page 3 lines 4, 9-16, page 6 lines 28-31, page 7 lines 1-4 and on page 4 lines 4-21. Support for new claim 15 is found on page 3 lines 3-4, page 4 lines 4-23, page 5 lines 1-14 and page 7 lines 1-4. Support for new claim 16 is found on page 6 lines 1-6 and page 7 lines 8-10. Support for new claim 17 is found on page 7 lines 1-4. Support for new claim 18 is found on page 6 lines 1-6 and 28-31 and page 7 lines 1-4 and lines 8-10. Support for new claim 19 is found on page 4 line 25. Support for new claim 20 is found on page 4 lines 25-26. Support for new claim 21 is found on page 4 line 26. Support for new claim 22 is found on page 7 lines 1-4. Support for new claim 23 is found on page 6 line 4. Support for new claim 24 is found on page 7 lines 16-18. Support for new claim 25 is found on page 6 lines 1-6 and p. 2 lines 20-23. Support for new claim 26 is found on page 6 lines 1-6 and page 7 lines 1-4.

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CONCLUSION

Applicants believe no new matter has been introduced by these amendments and the Examiner is respectfully requested to enter the amendments. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 328-4400.

Respectfully submitted,

Date: 1/9-02

Koren J. Anderson

Koren J. Anderson, Ph.D.
Reg. No. P-51,061

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) **VERSION WITH MARKINGS TO**
) **SHOW CHANGES**
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BOX PATENT APPLICATION

Assistant Commissioner for Patents
PO BOX 2327
Arlington, VA 22202

Sir:

The Examiner is respectfully requested to make the following amendments. A clean copy of the text of the claims is attached hereto (*See*, "Clean Copy of Claims").

In the Claims:

Cancel Claims 1-12

Add the following new Claims.

--13. (New) A composition comprising:

a hybridoma cell culture producing monoclonal antibodies which bind specifically to cocaine and cocaethylene and have low or no cross reactivity with benzoyl ecgonine.

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Robert Pattison

(Printed Name)

Robert Pattison

14. (New) The hybridoma cell line according to Claim 13, wherein said cell line is produced from a host immunized with an immunogen comprising at least one cocaethylene hapten conjugated to an antigenic protein, wherein said cocaethylene hapten comprises N-methyl tropane substituted at the 2-position with a carboxyethyl group and at the 3-position with a benzoyloxy group, wherein the benzyoyloxy group is substituted at the para position with an aliphatic linking group of from 1-6 atoms, and said linking group comprises carbon atoms and 0 to 2 heterotaoms, said heteroatoms consisting of oxygen and nitrogen, wherein said aliphatic linking group terminating in said antigenic protein.
15. (New) The hybridoma cell line according to Claim 13, wherein said cell line is produced from a host immunized with an immunogen comprising at least one cocaethylene hapten conjugated to an antigenic protein, wherein said cocaethylene hapten comprises N-methyl tropane substituted at the 2-position by carboxyethyl or N-ethylcarboxamnide and at the 3-position by benzoyloxy or benzamido, wherein bonded at the para position of said benzoyloxyl or benzamido is a linking group or a carboxy group is attached to said linking group, wherein at least one of the substituents has an amido group, and wherein said bonding to the antigenic protein is through said carboxyl group.
16. (New) A monoclonal antibody produced by a hybridoma cell according to any one of Claims 13 to 15
17. (New) A hybridoma cell line produced by fusing spleen cells from a host immunized with an immunogen according to Claim 15 with immortalized host B cells, wherein said hybridoma cell line produces a monoclonal antibody which reacts with cocaine and cocaethylene and has low or no cross reactivity with benzoyl ecgonine.
18. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is

bovine serum albumin.

19. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is keyhole limpet hemocyanin.
20. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is tetanus toxoid.
21. (New) A monoclonal antibody produced by a hybridoma cell line according to any one of Claims 17-20.
22. (New) A monoclonal antibody according to Claim 21, wherein said monoclonal antibody is classified IgG, or equivalent thereof.
23. (New) A monoclonal antibody, which binds specifically to cocaine and cocaethylene and has low or no cross reactivity to benzoyl ecgonine.
24. (New) A monoclonal antibody according to Claim 23, labeled with an agent capable of providing a detectable signal.
25. (New) A monoclonal antibody according to Claim 23, wherein said monoclonal antibody has an affinity of at least 5×10^8 for cocaine and cocaethylene and a comparatively low affinity for benzoyl ecgonine, wherein said monoclonal antibody is classified as IgG, or equivalent thereof.
26. (New) A composition comprising a monoclonal antibody according to Claim 23.--

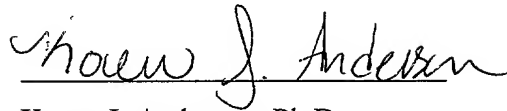
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Respectfully submitted,



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Sir:

The following is a clean copy of the claims with the amendments as shown on the attached "Version with Markings to Show Changes Made".

In the Claims:

13. (New) A composition comprising:
a hybridoma cell culture producing monoclonal antibodies which bind specifically to cocaine and cocaethylene and have low or no cross reactivity with benzoyl ecgonine.
14. (New) The hybridoma cell line according to Claim 13, wherein said cell line is produced from a host immunized with an immunogen comprising at least one cocaethylene hapten

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Robert Pattison
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Robert Pattison
(Printed Name)

conjugated to an antigenic protein, wherein said cocaethylene hapten comprises N-methyl tropane substituted at the 2-position with a carboxyethyl group and at the 3-position with a benzoyloxy group, wherein the benzyoyloxy group is substituted at the para position with an aliphatic linking group of from 1-6 atoms, and said linking group comprises carbon atoms and 0 to 2 heterotaoms, said heterotaoms consisting of oxygen and nitrogen, wherein said aliphatic linking group terminating in said antigenic protein.

15. (New) The hybridoma cell line according to Claim 13, wherein said cell line is produced from a host immunized with an immunogen comprising at least one cocaethylene hapten conjugated to an antigenic protein, wherein said cocaethylene hapten comprises N-methyl tropane substituted at the 2-position by carboxyethyl or N-ethylcarboxamide and at the 3-position by benzoyloxy or benzamido, wherein bonded at the para position of said benzoyloxyl or benzamido is a linking group or a carboxy group is attached to said linking group, wherein at least one of the substituents has an amido group, and wherein said bonding to the antigenic protein is through said carboxyl group.
16. (New) A monoclonal antibody produced by a hybridoma cell according to any one of Claims 13 to 15
17. (New) A hybridoma cell line produced by fusing spleen cells from a host immunized with an immunogen according to Claim 15 with immortalized host B cells, wherein said hybridoma cell line produces a monoclonal antibody which reacts with cocaine and cocaethylene and has low or no cross reactivity with benzoyl ecgonine.
18. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is bovine serum albumin.
19. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is

keyhole limpet hemocyanin.

20. (New) The hybridoma cell line according to Claim 17, wherein said antigenic protein is tetanus toxoid.
21. (New) A monoclonal antibody produced by a hybridoma cell line according to any one of Claims 17-20.
22. (New) A monoclonal antibody according to Claim 21, wherein said monoclonal antibody is classified IgG, or equivalent thereof.
23. (New) A monoclonal antibody, which binds specifically to cocaine and cocaethylene and has low or no cross reactivity to benzoyl ecgonine.
24. (New) A monoclonal antibody according to Claim 23, labeled with an agent capable of providing a detectable signal.
25. (New) A monoclonal antibody according to Claim 23, wherein said monoclonal antibody has an affinity of at least 5×10^8 for cocaine and cocaethylene and a comparatively low affinity for benzoyl ecgonine, wherein said monoclonal antibody is classified as IgG, or equivalent thereof.
26. (New) A composition comprising a monoclonal antibody according to Claim 23.

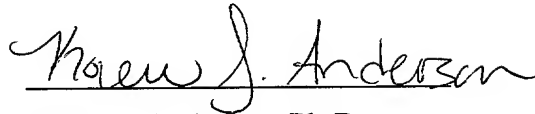
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